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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,835

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Rolf Muller

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BACHMAN & LAPOINTE, P.C.

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EXAMINER

ANDERSON, JERRY W

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,835	Applicant(s) MULLER ET AL.	
	Examiner JERRY W. ANDERSON	Art Unit 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/24/2010 has been entered. Claim 1 is amended, claims 3 and 5 are cancelled, claim 17, new, and claims 1, 2, and 6-17, pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1 and 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 is amended by changing the term limitation "the start network is at least partially" to "the starch network is retained". The new claim 17 contains the latter term. This is a broadening of the claim.

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4. The applicant states that support is found in ¶ 18 of the specification, but this is a reference to the second part of the amendment regarding the amount of short chain amylose in the starch.
5. The applicant has not provided support for the aforesaid amendment.
6. Retention of the network, the starch network made of crystallites of SCA, means in the broadest reasonable interpretation that the network is retained during incorporation, processing and final manufacture of foodstuffs.
7. However the specification states that during bread baking the network cannot be formed, (¶ 33, specification) and in the flaking process networks are largely destroyed. (¶ 28, specification)
8. The original disclosure as filed does not support the amendment.
9. This is a new matter rejection. Appropriate correction is required

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 1-2, 3, 6-7, and 11-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Y-C. Shi. (6,890,571)

13. Regarding the limitations added by amendment, these are product by process claims; the determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

14. Regarding Claims 1 and 17, the Applicant claims a slow digestible starch, partially gelatinized, with a DSC melting point is >60 deg C, and initial hydrolysis rate (Ho) is reduced by > 10 %, and 3-60% Short chain amylose relative to the entire starch, Shi teaches a resistant, gelatinized starch, (lines 6-9 col. 3, lines 46-48 col. 4, '571,) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, (line 13-15 col. 1 '571) a DSC melting point of at least about 90 deg. C (line 50-53 col. 4 '572), and digestibility being reduced to less than 50 % in two hours, (lines 5-14 col. 1 '571)

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15. Further, Shi discloses that the reaction is continued until a slowly digestible starch is achieved, up to 24 hours, (lines 31-33, col. 3, '571) and the short chain amylase content is about 98 % (line 44-48 col. 3 '571) and is highly crystalline short chain amylose, (lines 46-28 col. 4 '571) optionally the enzyme may be deactivated. (lines 51, col. 3, '571) The debranched starch may be characterized by the dextrose equivalent (DE), the reducing power of the hydrolysate, anhydrous glucose is 100 and unhydrolyzed starch is zero.

16. Regarding the amount of short chain amylase in samples 1A-1D, Shi discloses that for 1A the reaction was stopped at DE 6.0, 1B after 8 hours, 1C after 16 hours, and 1D at DE 5.3. (lines 53, col.7 -lines29, col. 8, '571) The data in table 1 shows that 1A and 1C are similar as is 1B and 1D, and since 1B and 1D are characterized by having a shorter reaction time and reacting to a less DE value, one of ordinary skill in the art would conclude that the amount of short chain amylose produced was likewise lower. Considering the below discussion, one of ordinary skill in the art would find it obvious that if Shi's starch products have the same characteristics as the instant applications then, logically it follows that the composition must be similar. From the standpoint of patent law, a compound and all of its properties are inseparable. (In re Papesch, 315 F.2d 381, 137 USPQ 43, 51 CCPA 1963)

17. It would be obvious to one of ordinary skill in the art that the instant invention, samples WS-571-4 and Shi's data from sample set 1, listed in tables 1 and 2, show the same characteristics and therefore must have similar compositions that result is said characteristics, i.e. the amount of resistant starch, or short chain amylose must be

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similar, since the samples of the instant invention state the sca is about 20 %, then it follows that the prior art must also contain sca of about 20 %. Wherein this falls within the applicant's range of 3-60%.

18. Regarding claim 2, Shi in '571 discloses the claimed invention, including hydrolysis rate being constant for at least 10 min, and less than 600 %/hr, as discussed below. The applicant determines the hydrolysis rate by measuring the amount of undigested starch at intervals of 15, 30, 45 and 60 minutes and calculating the digested portion of the starch. This data is plotted in Figures 1, 2, and 3. (pg 49 Applicant's specification) Shi measures the amount of glucose generated in the digestion reaction to give the digested portion of the starch at 20 min and 120 min. (lines 13-15 col. 7 '571) defines a rapidly digestible starch as being totally digested within 20 minutes. (lines 52-54 '571) Shi compares the amount of digested starch at 120 minutes with the amount at 20 minutes, to arrive at an estimate of the resistant starch. (lines 22-27 col. 7 '571) In the Applicant's data, Shi's rapidly digestible starch corresponds to Fig 1 Kellogg's corn flakes, and Fig. 3, Sample set WS-57 1-4. Applicant in Table 2 lists the Ho%/h for sample set WS-57-1 from 800 to 1000. Shi in Tables 1 and 2 lists the amount of starch digested at 20 minutes ranging from 20 to 50 % of the total starch, and 120 minutes from 50 to 70 % digested. (Table 1 '571) Shi's slowly digestible starch fraction, in Table 1 is about 24 %/120 minutes or about 14.5 percent per hour. Comparable with the Applicant's values of 30 per cent per hour, Sample KS-1 Table 2, Applicant. However, as per the Applicant's Figs, 1-3 the curve is non-linear versus time, and thus, Shi's results are lower than the Applicants for digestion per hour. Looking at the 20 min

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values for Shi, and comparing to the Applicant's 15 and 30 minute values, it can be seen that the results for both methods are overlapping. (Table 1 and 2, '571, Figs. 1 and 2 Applicant)

19. Regarding claim 4, Shi discloses the claimed invention, as discussed above, including the DSC melting point of at least 70 deg. C. (lines 50-53 col. 4 '571)

20. Regarding claims 6, 7, 11, 12, 13, 14, 15 and 16, are dependent upon claim 1, and detail the process by which the food stuff in claim 1 is prepared. As discussed above, Shi teaches a resistant, gelatinized starch, (lines 6-9 col. 3, lines 46-48 col. 4, '571) a starch that is resistant to digestion in the small intestine, and passes into the large intestine, (line 13-15 col. 1 '571) a DSC melting point of at least about 90 deg. C (line 50-53 col. 4 '572), and digestibility being reduced to less than 50 % in two hours. (lines 5-14 col. 1 '571) Unless the claims listed herein add some patentably distinct characterization to the foodstuff, then said foodstuff is anticipated by Shi. ('571)

21. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Y-C. Shi, (6,890,571) in view of Y-C. Shi. (5,593,503)

22. These are product by process claims, the determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).A product-by-process limitation adds no patentable distinction to the

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claim, and is unpatentable if the claimed product is the same as a product of the prior art.

23. Regarding claims 8 and 9, '571 and '503 disclose the claimed invention, as discussed above, including food products, cereal, bread, crackers, cookies, pasta, coated and fried foods, made using said modified starch. (Lines 40-45 col. 4, Claim 27 '503)

24. '571 and '503 are analogous art in the both are concerned with the modification of starches to form a starch that is resistant to digestion in humans.

25. It would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the teachings of '571 and '503 in order to produce a food product that is likely to be a factor in the prevention of diverticulosis and colon cancer. (lines 30-32 col. 1 '503), and to produce a resistant starch that may contribute to reducing the risk of developing diabetes, or be useful in the treatment of hyperglycemia and obesity. (lines 36-40 '571)

26. Regarding claim 10, '571 and '503 disclose the claimed invention, as discussed above, including a discussion of increased organoleptic qualities such as crispiness, or preservative effects in those food products have good taste and appearance. (line 46, col. 9 '503, have acceptable mouthfeel and flavor, (line 67 col. 9, lines 30-31 col. 10, '503).

Response to Amendment

27. The applicant having amended claim 1 and added new claim 17, wherein the claims contain the limitation “the starch network is retained”, which is not supported by the original disclosure, A 35 USC 112 1st rejection is instituted.

28. The applicant having amended claim 1, the 35 USC 102(b) rejections are withdrawn, and a 35 USC 103(a) rejection instituted.

Response to Arguments

29. Applicant's arguments filed 2/24/2010 have been fully considered but they are not persuasive.

30. The applicant states that the product of the instant invention is a gel and is therefore distinguishable from the prior art.

31. Unfortunately, the applicant has chosen to use product by process claims.

32. The end result of the applicant's process is a product with similar characteristics as the prior art. It matters not if the applicant states that during the process a gel is formed, the end result is a starch containing cooked food that exhibits the same characteristics as the prior art.

33. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process

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limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art. Furthermore, the burden shifts to applicant, who has chosen to describe his *product* by using physical characteristics that the Office has no resources to compare with prior art products by manufacturing the prior art product and making comparisons therewith. It is being assumed that since the reference has a similar product, made in a similar way, then the new feature being claimed must be present.

34. It is well known that crystallization of starch produces a form of starch that is resistant to digestion, (Example 1, lines 43-67, col. 6, table 1, '503) Having formed a crystallite using the short chain amylose, which forms a resistant starch, that can be dried, ground and used in foodstuffs, (lines 20-51, col. 9, '571), it is obvious to one of ordinary skill in the art that further mixing of the short chain amylose, with a native starch, following by crystallization, would, likewise, produce a resistant starch.

Resistance to digestion is an inherent quality of crystallized starches. While the applicant has investigated and determined ranges and parameters optimal for the formation of starch crystallites, Shi, has, likewise, determined conditions conducive to the formation of similar resistant starches. (Table1, Table 2, and Table 3, '503)

35. One of ordinary skill in the art would have considered the invention to have been obvious because the parameters for the formation of the resistant starches of the prior art overlap the instantly claimed parameters and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed

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ranges from the range disclosed in the prior art reference, particularly in view of the fact that: "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages" In re Peterson, 65 USPQ2d 1379 (CAFC 2003)

36. Regarding the applicant arguments (p11-12) regarding the combination of Shi and Shi, the applicant is apparently mis-reading the prior art. The applicant states that Shi ('503) mention dietary fiber in the abstract, and concludes that dietary fiber is indigestible, and thus is not applicable in the rejection of the instant application.

37. The goal of the instant application and the prior art is to make slowly digestible starch, which will pass through the small intestine into the colon where it will be fermented by bacteria. (lines 10-15, col. 1, '571) There are two advantages resulting from this, the decreased glycemic response, and the lower calorie yield, since the fermentation products, volatile fatty acids, contribute only 1-2 calories per gram, versus about 7 for carbohydrates.

38. Shi states that he equates resistant starch and dietary fiber. (lines 23-25, col.4, '503) Therefore Shi is not referring to nondigestible fiber in the abstract.

39. As to the combining of Shi and Shi, the examiner submits that the references are merely two aspects of the same inventive procedure, which is the generation of crystalline structures of starch, or crystallites as per the applicant, wherein the crystalline starch structures resist attack the digestive acids and enzymes and are processed in the large intestine. Low amylose starch must be hydrolyzed to produce

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the short chain amylose, and remove the amylopectin starch. High amylose starch can be used as is. Then the starch are heated with water and allowed form the crystalline structures. Such structures survive drying and can be incorporated into other starch containing foods to increase the resistant starch content.

Conclusion

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY W. ANDERSON whose telephone number is (571)270-3734. The examiner can normally be reached on 7 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. SAYALA/
Primary Examiner, Art Unit 1781

/J. W. A./
Examiner, Art Unit 1781